REMARKS

Claims 1-31 are pending.

Claims 22-30 have been withdrawn in view of Applicant's restriction election.

Claims 1-21 and 30 stand rejected by the Examiner.

Claims 1, 11, 12, 13, 20, and 21 have been amended herein.

Claim 31 has been cancelled herein without prejudice.

Applicant thanks the Examiner for indicating that the drawings are acceptable, acknowledging receipt of Applicant's priority documents, for reviewing Applicant's IDS dated June 18, 2008, and for joining claims 11-21 and 30 with claims 1-10 for examination.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 12, 13, 20, and 21 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness in view of lack of antecedent basis for recitation of "the adherent sacrificial composition."

Applicant has amended claims 12, 13, 20, and 21 to recite "the adherent antimicrobial barrier composition" in place of "the adherent sacrificial composition" as suggested by the Examiner.

Applicant, therefore, respectfully requests withdrawal of this rejection.

Rejection under 35 U.S.C. § 103

The Examiner has rejected claims 1-10, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Baker, Jr. et al. (U.S. Patent No.6,635,676) (hereinafter "Baker") in view of Beerse et al. (U.S. Patent No. 6,294,186) (hereinafter "Beerse").

The Examiner states that Baker and Beerse teach the elements of Applicant's claims as follows:

Claim 1:

column 12, lines 1-13; column 13, lines 12-25; column 14, lines 1-15; column 40, line 50 to column 41, line 25 (adherent antimicrobial barrier composition); column 41, lines 1-15 (gelling agent) (Applicant respectfully points out, however, that the only gelling agents mentioned in Baker et al., is starch.)

Claim 2:

column 22, lines 40-59 (about 0.1-15% ethanol)

Claim 3:

The Examiner states that Baker does not appear to disclose that the gelling or thickening agent comprises sodium alginate at a percentage of 0.1-4 of the total composition, but that Beerse discloses a method for reducing the transfer of contamination from a contaminated surface by coating the surface with an adherent antimicrobial barrier composition (column 1, line 56 to column 2, lines 13; column 3, lines 49-62), a gelling or thickening agent comprising sodium alginate at a percentage of about 3% (concerning claim 3; column 9, lines 55-65; column 10, lines 39-43) in order to allow said composition to form into a gel for greater adhering properties (column 9, lines 55-65), and that it would have been obvious to combine the use of sodium alginate of Beerse with the compositions of Baker to arrive at Applicant's claimed invention. (Applicant respectfully points out, however, that neither Baker nor Beerse teaches the use of pectin, methylated pectin, gelatin, hydrosylated gelatin, agar or carrageenan as gelling of thickening agents.)

Claim 4:

column 27, lines 35-50 (about 1-5% of lecithin)

Claim 5:

column 23, lines 46-53; concerning claim 5 (about 1-5% of Tween 80)

Claim 6:

column 22, lines 40-45 (about 0.1-15% of cetylpyridinium chloride)

Claim 7:

column 23, lines 25-48 (antimicrobial agent is an alcohol)

Claims 8 and 9:

column 30, lines 45-50 (heating is an antimicrobial agent) (Applicant respectfully points out however that heating in Baker is for mixing (heating prior to mixing) and is not for use as an antimicrobial agent.)

Claim 10:

column 39, lines 25-50 (liquid or a gel)

Applicant's traversal:

Applicant respectfully traverses the rejection based on the presently recited claim amendments, and in view of the limited teaching of Baker and Beerse. Neither Baker nor Beerse teaches, suggests, or motivates a method of reducing or preventing transfer of microbial contamination to or from a surface being cut as presently claimed. Additionally, the general mention of "gels" or "gelling agents by Baker is not taught as relating to use on surfaces and is not in a context which would reasonably suggest or motivate an "adherent" barrier. Moreover, the mode of Beerse comprises *transient* application of benzoic acid in order to achieve a specific anti-virus action caused by a specific antimicrobial. There is no suggestion whatsoever in Beerse that an "adherent" barrier acts to physically block access by microorganisms, and the Beerse applications, such as application to human or hard surfaces (column 4, lines 1-5), obviously do not involve a thick "adherent" barrier. Applicant respectfully contends that the asserted rejection is improperly premised on hindsight, particularly in view of the fact that aspects of Beerse actually *teach away* from Applicant's claimed subject matter as discussed below.

Analysis:

As an initial matter, independent claim 1 has been amended to recite:

"A method of reducing or preventing transfer of microbial contamination to or from a ~~contaminated~~ surface being cut; comprising:

providing a surface to be cut;

providing a cutting implement;

coating at least one of the~~a contaminated~~ surface and the cutting instrument~~or a portion thereof~~ with a adherent antimicrobial barrier composition, comprising:

from about 0.1 to about 25% (wt) of a gelling or thickening agent,[[;]]

from about 0.1 to about 10% (wt) of an emulsifier or stabilizer,[[;]]

from about 0.05 to about 10% (wt) of a surfactant,[[;]] and

an antimicrobial agent; and

cutting through the surface with the cutting instrument, wherein at least part of the adherent antimicrobial barrier composition is transferred between the surface and the cutting instrument during cutting, and wherein~~whereby~~ transfer of microbial contamination to or from the surface is reduced or precluded."

The amendments serve to further clarify the distinguishing features of Applicant's claimed subject matter.

At page 3, paragraph 7, of the Office Action, the Examiner states:

> *Baker discloses a method of reducing or preventing transfer of contamination from a contaminated surface, comprising coating a contaminated surface with an adherent microbial barrier .... comprising ... a gelling agent (column 41, lines 1-15).*

Baker. Baker, however, discloses many uses other than action as a barrier, including uses that involve eating of the compounds as by humans or animals (column 4, line 62) and injection

of the compounds under the skin or into muscles (column 5, lines 1-10). Accordingly, the general mention of "gels" or "gelling agents by Baker is not reasonably taught as relating to use on surfaces and is not in a context which would reasonably suggest or motivate an "adherent" barrier. Gels, as taught by Baker serve purposes in proposed compositions other than promoting adhesion, such as providing food bulk, mouth feel for ingestible compositions, or release rate control functions for injected compositions. The context of the quoted passage in Baker has *nothing* in particular to do with adherent barriers, as is clear from the other items listed along with "gels" in the list, including such things as dyes and perfumes, which have *nothing* to do with an adherent barrier. A person of ordinary skill reading the quoted portion of Baker would clearly not relate "perfumes" to a barrier application, and thus would not relate gels either. The teachings of Baker at this point is so general and vague as not to teach anything about barriers at all. Applicant respectfully points out that it is only in hindsight that the Examiner relates that the generalized and vague cataloging of ingredients in the quoted passage with one particular use, among many other, listed by Baker.

Beerse. With respect to Beerse, the Examiner states that an adherent microbial barrier is taught at various locations (column 1, line 56, to column 2, line 13, and column 3, lines 49-62). However, upon close reading, there is found no suggestion whatsoever that an "adherent" barrier acts to physically block access by microorganisms. Rather, the main teaching of Beerse is that viruses may be inactivated by contact with a particular antimicrobial, benzoic acid, when this is applied to the skin. The proposed applications such as application to human, or application to hard surfaces (column 4, lines 1-5), obviously do not involve a thick "adherent" barrier, since, clearly, it would be undesirable to have a thick coating of substance on a floor or countertop, or on human skin. Rather, the mode of Beerse appears to be, and would be understood to be, *transient* application of benzoic acid in order to achieve a specific anti-virus action caused by a specific antimicrobial. Additionally, Beerse (at column 4, lines 15-25) is highly suggestive that a thick coating is not intended, since the claimed antimicrobial action persists only for a few hours, at most. Moreover, as described by Beerse (at column 17, lines 34-40), the purpose of a gel

additive is not to provide adhesion, but rather to provide particular "rheological characteristics" to the composition.

In the above respects, therefore, Beerse actually ***teaches away*** from Applicant's claimed subject matter. This conclusion is bolstered by the discussion in Beerse (at column 12, lines 40-45), which indicates that low viscosity emulsions are preferred over those which are high viscosity, presumably more adherent, emulsions. Accordingly, due to the different motives for the use of gels in Beerse, a person of skill in the relevant art looking for information about "adherent" coatings would not be motivated to follow or utilize the Beerse teachings and would actually be discouraged from doing so.

Finally, as acknowledged by the Examiner, neither Baker nor Beerse teaches, suggests, or motivates use of a cutting implement, or a method of reducing or preventing transfer of microbial contamination to or from a surface <u>being cut</u> as presently claimed.

Applicant, therefore, respectfully requests withdrawal of the Examiner's obviousness rejection based on Baker in view of Beerse, based on Applicant's claim amendments and attendant rebuttal arguments.

Further rejection under 35 U.S.C. § 103

The Examiner has rejected claims 11-21 and 31 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Baker in view of Beerse, as applied to claim 1 above, and further in view of Iwai (U.S. Publication No. 2003/0100254) (hereinafter "Iwai").

The Examiner states that " Baker does not appear to specifically disclose that the composition is coated onto the target surface prior to cutting through the target surface, or that a cutting element is utilized in a food process industry. Iwai discloses a method for reducing or preventing transfer of contamination from a contaminated surface, comprising coating a contaminated surface with an antimicrobial composition (paragraphs 13 and 26-31; Figure 1). The reference continues to disclose that the surface is coated prior to cutting through said surface with the antimicrobial composition to provide a sacrificial layer that is partially transferable

between the surface and the cutting implement during cutting; and further discloses cutting through the layer on the surface with the cutting implement to provide a protective layer to the cutting implement surface in order to ensure that a target surface such as meat is completely sterilized before being distributed (paragraphs 37-40, 46 and 47; Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to coat the surface prior to cutting the surface with the antimicrobial composition to provide a sacrificial layer that is partially transferable between the surface and a cutting implement during cutting; and cutting through the layer on the surface with the cutting implement to provide a protective layer to the cutting implement surface in order to ensure that a target surface such as meat is completely sterilized before being distributed as exemplified by Iwai."

Applicant's traversal:

Applicant respectfully traverses this rejection, based on the fact that while Iwai may arguably teach cutting, this teaching is of cutting in the sole and required context of a transient aqueous washing solution where contact between the solution and the meat is limited to only short periods. The Examiner's assertion of the combination of Baker, Beerse, and Iwai, therefore, is unsupportable because, as discussed below in detail, in combining the teachings of Iwai with those of Baker and Beerse, the Examiner has not considered each reference "as a whole" as required under U.S. patent law, and would also render the references unsatisfactory for there respective intended purposes (MPEP § 2143.01).

Analysis:

With respect to the Iwai reference, the Examiner (Office Action, page 5, second paragraph) states:

> *Iwai discloses a method for reducing or preventing transfer of contamination from a contaminated surface, comprising coating a contaminated surface with an antimicrobial composition, to provide a sacrificial layer that is partially transferable between the surface and the cutting implement to provide a protective layer to the cutting implement surface in order to insure that the target surface such as meat is completely sterilized before being distributed (paragraphs 37-40, 46 and 47, Figure 1).*

Iwai. Applicant respectfully points out that there are, in fact, no teachings whatsoever in Iwai of use of an adherent "protective layer". Rather, Iwai teaches an aqueous washing solution which may even be applied in the form of "mist" continuously generated in a "chamber" (Iwai at page 3, paragraph 0040-0041, also 0044). Iwai, therefore, operates not by applying a "layer" but rather by continually applying a mist, or by repeatedly applying a non-adherent, non-persistent solution, for short periods of time (Iwai at paragraph 0047). This is a fundamentally different mode of operation than applying an adherent layer containing a gel as presently claimed. Iwai teaches nothing more than simply washing of a carcass with a water solution, and moreover directly ***teaches away*** from the idea of a persistent coating, by indicating that contact between the solution and the meat should be limited to only short periods of seconds, in order to avoid excessive water absorption by the meat (Iwai at paragraph 0047).

APPLICABLE LAW:

Obviousness. In *KSR International Co. v. Teleflex, Inc*. 127 S.Ct. 1727, 2007 (herein referred to as "*KSR*"), the Supreme Court stated that the Graham factors ((1) scope and content of the prior art, (2) difference between claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations; Graham v. John Deere Co., 383 U.S. 1 (1966)) continue to define the inquiry that controls the obviousness analysis. Additionally, under KSR, the TSM test is valid provided that such application does not require an overly rigid or explicit application of the asserted prior art. Accordingly, as already stated in the record, and in keeping with KSR, to establish a *prima facie* case of obviousness there must be: (i) a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art (POSITA), to modify the reference or to combine reference teachings; (ii) a reasonable expectation of success; and (iii) the prior art reference(s) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and knowledge generally available to POSITA, and not based on Applicant's

disclosure (*In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); and see MPEP §§ 2143-2143.03). Therefore, to support a conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. Moreover, there can be no reasonable expectation of success where the art, alone or in combination, *teaches away* from the invention.

Inventions and asserted references must be considered as a whole. *Importantly, e*ven where a *prima facie* case is established, such case is rebuttable, and the proper inquiry involves consideration of inventions as a whole (*In re O'Farrell*, 853 F.2d 894, 903 (1988). In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). In *Diamond v. Diehr* (450 US 175, 209 USPQ 1) (U.S. 1981), the *Diehr* Court determined "[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the [35 U.S.C. § 101] analysis." Claims have a synergistic effect, so that if a claim contains elements A, B, C, and D, it is not proper to attack each of A, B, C, and D in isolation as four separate elements. The USPTO and the courts must view the claim as a whole under 35 U.S.C. § 101.

Applicant respectfully points out, therefore, that under U.S. patent law, that when multiple references are asserted in combination, each reference must nonetheless be individually considered as a whole, and that the Examiner cannot, therefore, indiscriminately parse and combine elements from multiple references and ignore how those elements function in each reference "as a whole."

In the instant case, while Iwai may arguably teach cutting, this teaching is of cutting in the sole and required context of a transient aqueous washing solution where contact between the solution and the meat is limited to only short periods. The Examiner's assertion of Iwai, therefore, is unsupportable because in combining the teachings of Iwai with those of Baker and Beerse, the Examiner has not considered Iwai "as a whole" as required under U.S. patent law.

Likewise, not only is the general mention of "gels" or "gelling agents" by Baker not taught as relating to use on surfaces and is not in a context which would reasonably suggest or motivate an "adherent" barrier, but combination of gelling agents would be contrary to the requirement in Iwai of a transient aqueous washing solution and, thus, such combination ignores the references as a whole and would further render Iwai inoperable for its application render the references unsatisfactory for there respective intended purposes (MPEP § 2143.01). Similarly, the mode of Beerse comprises, *transient* application of benzoic acid in order to achieve a specific anti-virus action caused by a specific antimicrobial. There is no suggestion whatsoever in Beerse that an "adherent" barrier acts to physically block access by microorganisms, and the Beerse applications, such as application to human or hard surfaces (column 4, lines 1-5), obviously do not involve a thick "adherent" barrier.

Applicant respectfully contends that the asserted rejection is not supportable when, in considering the references in combination, each reference is nonetheless considered as a whole. Applicant further respectfully contends that the rejection is improperly premised on hindsight, particularly in view of the fact that aspects of Beerse actually *teach away* from Applicant's claimed subject matter as discussed below.

Applicant, therefore, respectfully requests withdrawal of the Examiner's obviousness rejection based on Baker in view of Beerse and in further view of Iwai, based on Applicant's claim amendments and attendant rebuttal arguments.

Respectfully submitted,
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